



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

May 31, 2016

Boston Scientific Corporation  
c/o Mr. Brian Park  
Principal Regulatory Affairs Specialist  
3574 Ruffin Road  
San Diego, CA 92123

Re: K070951

Trade/Device Name: Peripheral Cutting Balloon  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: PNO  
Dated: April 3, 2007  
Received: April 4, 2007

Dear Mr. Park:

This letter corrects our substantially equivalent letter of June 4, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Misti L. Malone -S**

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## II. INDICATIONS FOR USE STATEMENT

510(k) Number: K070951

**Device Names:**

2cm Peripheral Cutting Balloon®

small Peripheral Cutting Balloon® with Monorail Delivery System

small Peripheral Cutting Balloon® with Over-the-Wire Delivery System

**Indications for Use:**

The Peripheral Cutting Balloon catheters are indicated for percutaneous transluminal angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.


Prescription Use X  
(part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K070951

### III. 510(k) SUMMARY

JUN - 4 2007

<b>Submitter's Name and Address</b>	Boston Scientific Corporation 3574 Ruffin Road San Diego, CA 92123		
<b>Contact Name and Information</b>	Brian Park Principal Regulatory Affairs Specialist Phone: (858) 503-1822 Fax: (858) 292-8381		
<b>Date Prepared</b>	April 3, 2007		
<b>Proprietary Names</b>	2cm Peripheral Cutting Balloon® small Peripheral Cutting Balloon® with Monorail Delivery System small Peripheral Cutting Balloon® with Over-the-Wire Delivery System		
<b>Common Name</b>	PTA Catheter		
<b>Product Code</b>	LIT		
<b>Classification of Device</b>	Class II, 21 CFR Part 870.1250		
<b>Predicate Device</b>	2cm Peripheral Cutting Balloon®	K041993 K051254	August 16, 2004 June 22, 2005
	Small Peripheral Cutting Balloon® with Monorail Delivery System	K052038 K062387	August 16, 2005 October 5, 2006
	Small Peripheral Cutting Balloon® with Over-the-Wire Delivery System	K052038	August 16, 2005
<b>Device Description</b>	The family of Peripheral Cutting Balloon (PCB) Catheters has features of a conventional angioplasty catheter with advanced microsurgical capabilities. The PCB family features a balloon with 3 or 4 atherotomes (microsurgical blades) mounted longitudinally on its outer surface. The device is inserted over a guidewire and delivered to the target lesion. When the PCB device is inflated, the atherotomes score the plaque, creating initiation sites for crack propagation. Percutaneous Angioplasty (PTA) with the PCB device allows dilatation of the target lesion with less pressure, minimizing barotrauma.		

**Intended Use of  
Device**

PCB catheters are indicated for percutaneous transluminal angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

**Support of  
Substantial  
Equivalence**

There are no changes in design, composition, function or indication of any of the proposed PCB devices compared to their respective predicates:

<i>Proposed Device</i>	<i>Predicate Device</i>	<i>510(k)</i>	<i>Clearance Date</i>
2cm PCB	2cm PCB	K041993	August 16, 2004
		K051254	June 22, 2005
small PCB with Monorail Delivery System	small PCB with Monorail Delivery System	K052038	August 16, 2005
		K062387	October 5, 2006
small PCB with OTW Delivery System	small PCB with OTW Delivery System	K052038	August 16, 2005

The only change being proposed is adding a new contraindication and a new warning in the DFU.

**Conclusion**

Based on the indications for use and the technological characteristics, the PCB has been shown to be equivalent in intended use and is considered to be substantially equivalent to their respective predicate PCBs (K041993, cleared August 16, 2004; K051254, cleared June 22, 2005; K052038, cleared August 16, 2005; and K062387, cleared October 5, 2006.)